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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,533	12/02/2005	Tadashi Okiyama	057788-0318680	9144

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PILLSBURY WINTHROP SHAW PITTMAN, LLP
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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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09/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,533	Applicant(s) OKIYAMA, TADASHI	
	Examiner SHEFALI D. PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-11, 15-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 15, 16 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/26/2009, 05/22/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 19, 2009, has been entered.

Acknowledgments

2. In the reply, filed on June 19, 2009, Applicant amended claims 1, 8, 15, 17, 18, and 21.
3. Applicant added new claims 23 and 24.
4. Currently, claims 1-5, 7, 15, 16, and 21-24 are under examination.

Response to Arguments

5. Applicant's arguments with respect to claims 1-5, 7, 15, 16, 21, and 22 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter not previously presented in the claims into independent claims 1, 15, and 21.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 7, 15, 16, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin (US 5,961,497), and further in view of Cote (US 5,775,671).

In regards to claims 1, 15, and 23, Larkin teaches a mixture injection port (Figures 1-3) comprising:

- a. a channel tube unit (connector [10])
- b. a septum (seal [70]) covering one end of the channel tube unit [10] and having a slit (slit [74]) into which a tube member (cannula assembly [12]) is inserted

Larkin does not teach a circulating member provided in the channel tube unit [10] below the septum [70], the circulating member being separate from the channel tube unit. Cote teaches a mixture injection port (Figures 1, 2A, 3 and 4) with a circulating member (actuator [50]) that is separate from a channel tube unit (housing components [26][36]). The circulating member [50] comprises a plate portion (transverse wall [60]) arranged to change direction of flow of a first fluid injected from an inserted tube member (nozzle [12]) or a second fluid flowing from the other end of the channel tube unit [26][36] and an edge portion (perimeter wall [52]) that protrudes upwardly from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port, of Larkin, with a circulating member, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

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In regards to claim 2, in a modified port of Larkin and Cote, Larkin teaches that the channel tube unit [10] comprises:

- a. a body portion (housing [24]) whose opening (opening [34]) is covered by the septum [70] and that is provided with an inner cavity (central passageway [26]) for accommodating the septum that is deformed by the insertion of the tube member [12] (Figure 2)
- b. a leg portion that is provided with a narrow tube portion (tube [16]) having a smaller width than that of the inner cavity [26], wherein the narrow tube portion is configured to provide communication between the inner cavity and the other end of the channel tube [10] (Figures 1-2)
- c. a step formed between the inner cavity [26] and the narrow tube portion [16] (Figures 1-2)

Larkin does not teach a plate portion of a circulating member that is mounted on the step. Cote teaches that the plate portion [60] of the circulating member [50] is mounted on a step (disc [40]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the step, of the modified port of Larkin and Cote, with a plate portion mounted on the step, as taught by Cote, as the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

In regards to claim 3, in a modified port of Larkin and Cote, Larkin does not teach a plate portion. Cote teaches that a groove (spaces in between raised areas [58]) is formed on a surface

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of the inner cavity side of the plate portion [60] of the circulating member [50], the groove extending in a direction different from a direction from which the first fluid is injected from the inserted tube member [12]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of the modified port of Larking and Cote, with a groove, as taught by Cote, as the plate portion will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the plate portion (Abstract)(column 1, lines 36-38)(column 5, lines 1-9)(column 5, lines 23-40).

In regards to claim 7, in a modified port of Larkin and Cote, Larkin does not teach a circulating member. Cote teaches that a groove (spaces in between castellations [54]) for guiding the first fluid or the second fluid is formed on an inner circumferential surface and an outer circumferential surface of the edge portion [52] of the circulating member [50]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the modified port of Larking and Cote, with a groove, as taught by Cote, as the edge portion of the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

In regards to claim 16, Larkin does not teach a circulating member. Cote teaches that a first groove (spaces in between raised areas [58]) is formed on a surface of the plate portion [60] of the circulating member [50] and a second groove (spaces in between castellations [54]) is formed on a surface of the edge portion [52] of the circulating member. It would have been

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obvious to a person having ordinary skill in the art at the time the invention was made to modify the circulating member, of the modified port of Larking and Cote, with first and second grooves, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 1-9)(column 5, lines 23-40).

In regards to claims 21 and 22, Larkin teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 1-3), the mixture injection port comprising a channel tube unit [10] and a septum [70] covering one end of the channel tube unit and having a slit [74], the method comprising:

- a. inserting a tube member [12] into the slit [74] (Figure 1 to Figure 2) (column 7, lines 61-63)
- b. injecting a first fluid into the tube member [12] or a second fluid into an other end of the channel tube unit [10] (column 5, lines 8-20)(column 5, lines 30-35)
- c. circulating the first fluid or the second fluid towards the septum side (column 5, lines 8-20)(column 5, lines 30-35)
- d. guiding the first fluid to the other end of the channel tube unit [10] or the second fluid to a top portion of the tube member [12] (column 5, lines 8-20)(column 5, lines 30-35)

Larkin does not teach a circulating member provided in the channel tube unit [10] below the septum [70], the circulating member being separate from the channel tube unit. Cote teaches a

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mixture injection port (Figures 1, 2A, 3 and 4) with a circulating member (actuator [50]) that is separate from a channel tube unit (housing components [26][36]). The circulating member [50] comprises a plate portion (transverse wall [60]) arranged to change direction of flow of a first fluid injected from an inserted tube member (nozzle [12]) or a second fluid flowing from the other end of the channel tube unit [26][36] and an edge portion (perimeter wall [52]) that protrudes upwardly from a periphery of the plate portion and is arranged along an inner wall of the channel tube unit. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the port/method, of Larkin, with a circulating member, as taught by Cote, as the circulating member will enhance the ability of the user to flush thoroughly the interior volume of the port by allowing fluid to pass through both the interior and exterior flow paths of the circulating member (Abstract)(column 1, lines 36-38)(column 5, lines 23-40).

8. Claims 4, 5, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin and Cote, as applied to claim 2 above, and further in view of Arnett (US 5,817,069).

In regards to claims 4 and 24, in a modified port of Larkin and Cote, Larkin does not teach a circulating member. Cote does not teach that the plate portion [60] of the circulating member [50] is provided with a holding portion for engaging a narrow tube portion. Arnett teaches a mixture injection port (Figure 1, assembly [10]) wherein a plate portion (actuator [20]) is provided with a holding portion (second actuator end [98] and exterior surface [100]) for engaging a narrow tube portion (second end [32]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion, of

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the modified port of Larkin and Cote, with a holding portion, as taught by Arnett, as the holding portion of the plate portion will efficiently engage and position the plate portion with respect to the interior surface of the port (column 4, lines 8-26).

In regards to claim 5, in a modified port of Larkin, Cote, and Arnett, Larkin does not teach a plate portion. Arnett teaches a groove (second fluid passageway [106]: openings [108][110]) for guiding a first fluid or second fluid that is formed in the back face of the plate portion [20] and the holding portion [98][100] (Figure 1). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the plate portion and the holding portion, of the modified port of Larkin, Cote, and Arnett, with a groove, as taught by Arnett, as the groove of the plate portion and holding portion will allow fluid to freely flow through the groove from the inlet of the port to the outlet of the port in either direction (column 5, lines 25-32).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
09/07/2009

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767